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| 10/587,832 | 10/03/2006 | Kazunosuke Aida | 27562U | 2366 |

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| EXAMINER | |
|---|---|
| HUANG, GIGI GEORGIANA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1618 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/587,832 | AIDA ET AL. | |
| | Examiner | Art Unit | |
| | GiGi Huang | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application*

1. Claims 1-10 are present for examination at this time.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "support" is indefinite and unclear. It is unclear if the term support is drawn to the cover material or if it is a secondary support film material on top of an inner patch or if it is a secondary support film that is a component of the inner patch. It does not allow one of skill in art to determine the metes and bounds of the invention. For purposes of examination, it is interpreted as a cover layer, adhesive, secondary layer with drug layer, and removable sheet.

4. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "thickness of 12-30 pm" is indefinite. It is unclear if Applicant is attempting to form a support film with the thickness of 12-30 picometers (pm) as a picometer is one millionth-millionth of a meter ($1 \times 10^{-12}$) and would not be able to support a transdermal drug composition. For purposes of examination, it is presumed that the measurement is 12-30um.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "thickness of 1230 gm" is indefinite. It is unclear how "thickness" which is a measure of width, is translated through units of weight. For purposes of examination, it is presumed that the measurement is 12-30um.

6. The term "essential" in claims 1-10 is a relative term which renders the claim indefinite. The term "essential" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term does not indicate the specifics for whether the components are required in the claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tateishi et al. (WO 02/069942) in view of Liedtke (DE 3811564).

It is noted that U.S. Pat. Publication 2004/0096491 will be used as the translation for Tateishi et al. (WO 02/069942). All references will relate to the translation.

It is noted that there is machine translation from the EPO website for Liedtke (DE 3811564). All references will relate to the translation.

Tateishi et al. teaches a transdermal patch comprising a support, an acrylic adhesive layer, and a release paper. The support has a preferred range of 5 to 1000 um and can be formed from different supports including polyethylene terephthalate.

The adhesive is preferably formed from either 2-ethylhexyl acrylate-N-vinyl-2-pyrrolidone.1,6-hexane glycol dimethacrylate copolymer and/or 2-ethylhexyl acrylate.vinyl acetate copolymer. These preparations are preferred since they enhance both the skin permeability of the drug and preparation properties. These adhesives are commercially available and examples are DURO-TAK87-2097 and DURO-TAK87-9087. The adhesive can also include a plasticizer. It is noted that the term "obtained by" in claims 1-10 denotes a product by process limitation in which only the end product is the limitation for examination. The release paper can be from several materials including polyethylene terephthalate. Tateishi et al. teaches several specific examples of transdermal patches with the drug pergolide mesylate, DURO-TAK87-4098, plasticizer, and polyethylene terephthalate as the support and the release layer. (Abstract, Page 1, paragraph 12, Page 2, paragraph 20-25, Page 3, paragraph 32-34, Page 5, paragraph 41, Page 6, paragraph 52-53, Page 7, Example 3, paragraph 86-96, Example 4-1, paragraph 98-107).

Tateishi et al. does not expressly teach the incorporation of a cover material or the specific thickness of 12-30um.

Liedtke teaches the improved absorption of medicinal plasters form with an elastic foam/polymer barrier with polyethylene, an acrylic adhesive, a flexible barrier from polyethylene, a drug containing layer with a glue layer and the release foil. The

advantages of encasing the plaster and having the plaster supported with a foam pad are increased variation, technical simplification, increased durability due to the elasticity and soft consistency, improved contour attachment to the skin surface, and reduced pressure on the skin. This also has improved duration of storage, improved adhesion and better sealing. (Abstract, Paragraph 1, 4-6, 9-11).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the foamed polymer, cover layer, and adhesive, as suggested by Liedtke, and produce the instant invention. The increased stability, storage, skin attachment, and durability would be substantial improvements that would create better drug profiles and reduced peeling of the transdermal patch. It would be obvious to also use the same adhesive for the outer layer (e.g. DURO-TAK) as used in the patch taught in Tateishi for simplified production, reduced costs, (no need to produce an additional adhesive), compatibility, and is an acrylate base.

One of ordinary skill in the art would have been motivated to do this because improved patient compliance through better skin attachment and durability is desirable. Increased storage periods are also very desirable for manufacturers as it lower production costs.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to arrive at the thickness of 12-30 um utilizing routine optimization within the ranges taught by Tateishi and produce the instant invention.

It is obvious to vary and/or optimize the thickness provided in the transdermal position, according to the guidance provided by Tateishi, to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

One of ordinary skill in the art would have been motivated to do this because it is desirable to adjust the components in a transdermal system to maximize the best possible drug delivery profile and thereby increase market share.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Claims 1-2, 4-7, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arth et al. (U.S.Pat. No. 6461636) in view of Terahara et al. (WO 03/013611).

It is noted that U.S. Pat. Publication 2004/0241240 will be used as the translation for Terahara et al. (WO 03/013611). All references will relate to the translation.

Arth et al. teaches a transdermal therapeutic system (TTS) for pergolide and its salts, preferably mesylate. Examples 1-4 are drawn to pergolide mesilate in a TTS comprising a polyester release foil, a matrix mass comprising pergolide mesiliate, a 20um polyester support, a contact adhesive based on crosslinked acrylate copolymers, and then an outer cover of polyurethane encompassing the entire patch to the release film. The adhesives exemplified are of the Euradgit series comprising copolymers of methacrylic acid, acrylic acid, their esters, and variations thereof (Abstract, Col.2, lines 20-38, Col. 5, lines 35-40, Col. 6, Examples 1-4, lines 45-68, Col. 7, lines 1-44).

Arth et al. does not expressly teach the use of a methacrylic C8 acid ester with vinyl acetate or n-vinyl-2-pyrrolidone or a plasticizer.

Terahara et al. teaches that acrylic adhesives such as acrylate.vinyl acetate copolymers, 2-ethylhexyl acrylate.2-ethylhexylmetjacrylate.dodecyl methacrylate, and methyl acrylate.2-ethylhexyl acrylate copolymer are available commercially as the DURO-TAK acrylic series, Eudragit series, and TSR containing N-vinyl-2-pyrrolidone and are analogous. Terahara also teaches the inclusion of plasticizers in the adhesive and that support layers can be composed of several material including polyurethane, polyethylene, and polyethylene terephthalate.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute analogous materials and include plasticizers, as suggested by Terahara, and produce the instant invention. It would have been

obvious to one of skill in the art to try the analogous materials taught, as there are only two other commercial adhesives (DURO-TAK and TSR), that are analogous to Eudragit, and six other support materials other than polyurethane. One would add plasticizers, as they are known to improve skin irritation and removal.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have analogous choices to substitute the adhesives and support materials when motivated by pricing, availability, or desired properties of the in the final product. It is also desirable for manufacturers to add plasticizers as a reduction in skin irritation and improved removal are desirable qualities for patient preference and increasing marketshare.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arth et al. (U.S.Pat. No. 6461636) in view of Terahara et al. (WO 03/013611) as in claims 1-2, 4-7, 9-10, and further in view of Liedtke (DE 3811564).

The teachings of Arth et al. and Terahara et al. are discussed above.

Arth in view of Terahara does not expressly teach the use of foamed polymers.

Liedtke teaches the improved absorption of medicinal plasters with an elastic foam/polymer barrier with polyethylene, an acrylic adhesive, a flexible barrier from polyethylene, a drug containing layer with a glue layer and the release foil. The design construction is similar to the one taught by Arth except for the foamed polymer. The advantages of encasing the plaster and having the plaster supported with a foam pad is increased variation, is technically simpler, and increased durability due to the elasticity and soft consistency, improved contour attachment to the skin surface, and reduced pressure on the skin. This also has improved duration of storage, improved adhesion and better sealing. (Abstract, Paragraph 1, 4-6, 9-11).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the foamed polymer as suggested by Liedtke, and produce the instant invention. The increased stability, storage, skin attachment, and durability would be substantial improvements that would create better drug profiles and reduced peeling of the transdermal patch.

One of ordinary skill in the art would have been motivated to do this because improved patient compliance through better skin attachment and durability is desirable. Increased storage periods are also very desirable for manufacturers as it lower production costs.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have

had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Conclusion***

11. Claims 1-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER